

**HPTN 096**

# **Integrating Multi-Level Strategies to Reduce HIV Transmission Among Black MSM in the Southern US**

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**Yale School of Nursing**

**::: HPTN ANNUAL :::  
::: MEETING 2021 :::::**



# The HIV Epidemic in Black MSM and the Southern US: Prevalence

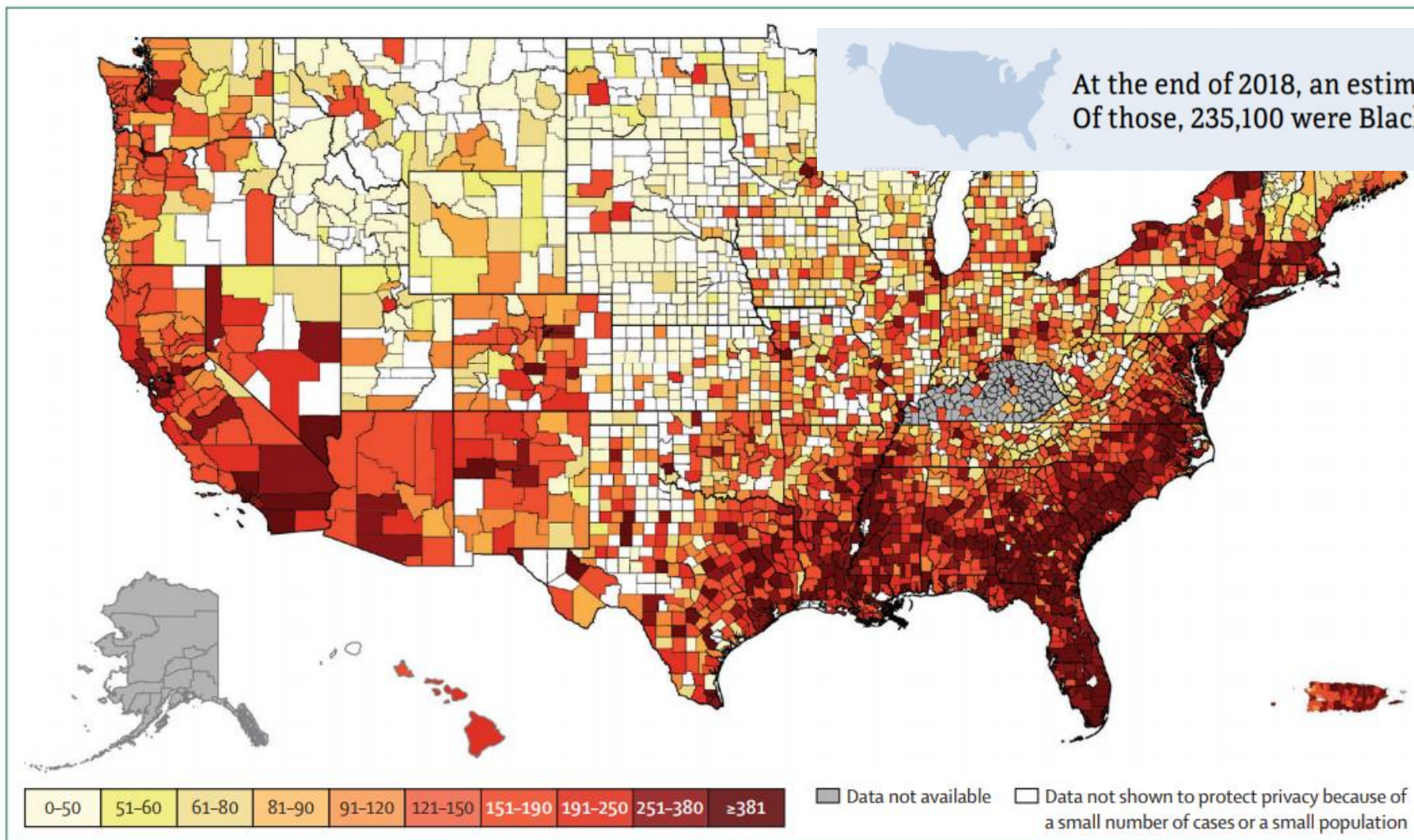


Figure 2: Diagnosed HIV prevalence by US county, 2018

P. Sullivan et al. **Epidemiology of HIV in the USA: epidemic burden, inequities, contexts, and responses**. Lancet. Published online February 19, 2021

CDC Fact Sheet, **HIV and African American Gay and Bisexual Men**, October 2020

# The HIV Epidemic in Black MSM and the Southern US: Diagnoses and Incidence

51%

Of the **37,968 NEW HIV DIAGNOSES** in the US and dependent areas in 2018, 51% were in the South.

26%

Of the **37,968 NEW HIV DIAGNOSES** in the US and dependent areas\* in 2018, 26% were among Black/African American† gay and bisexual men. ‡ \*\*

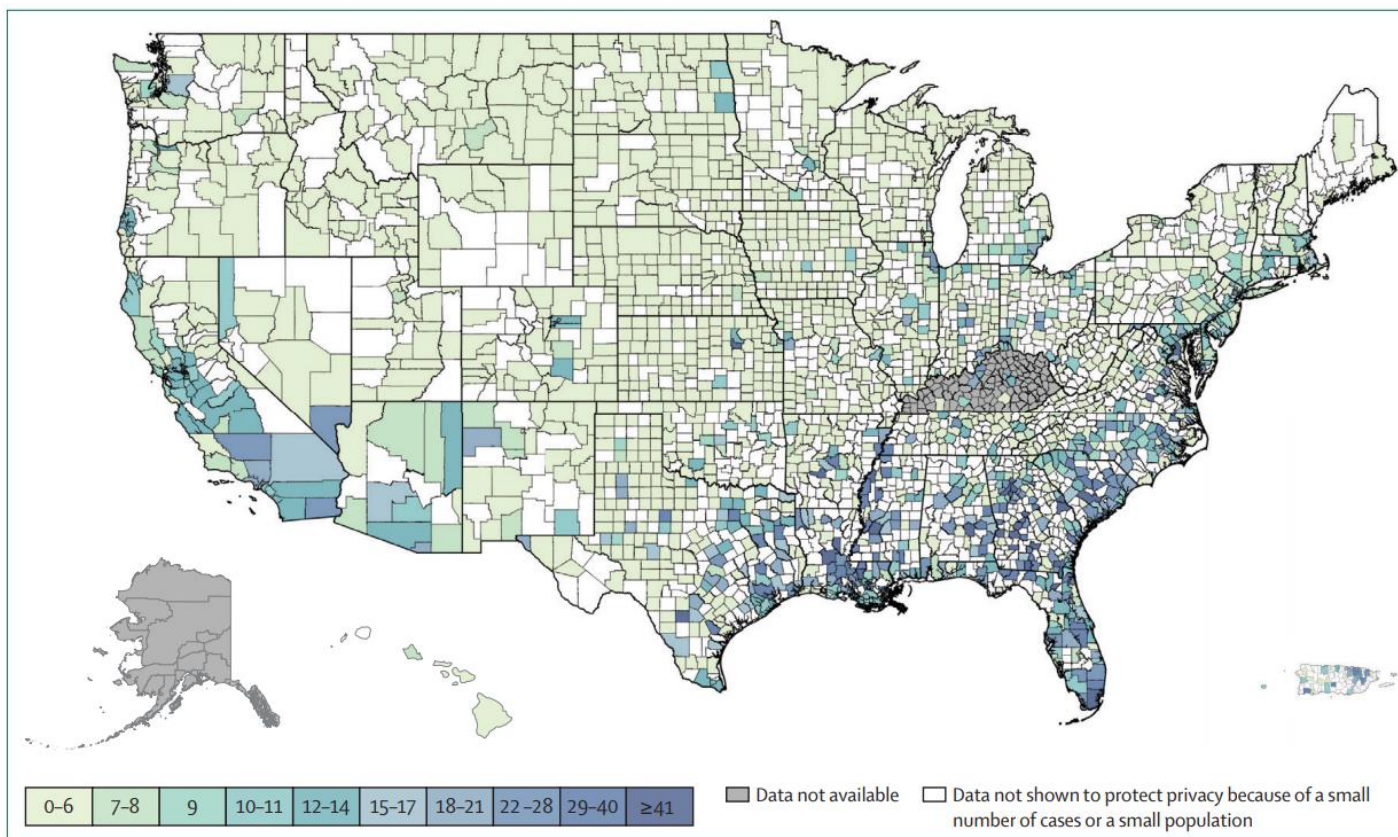
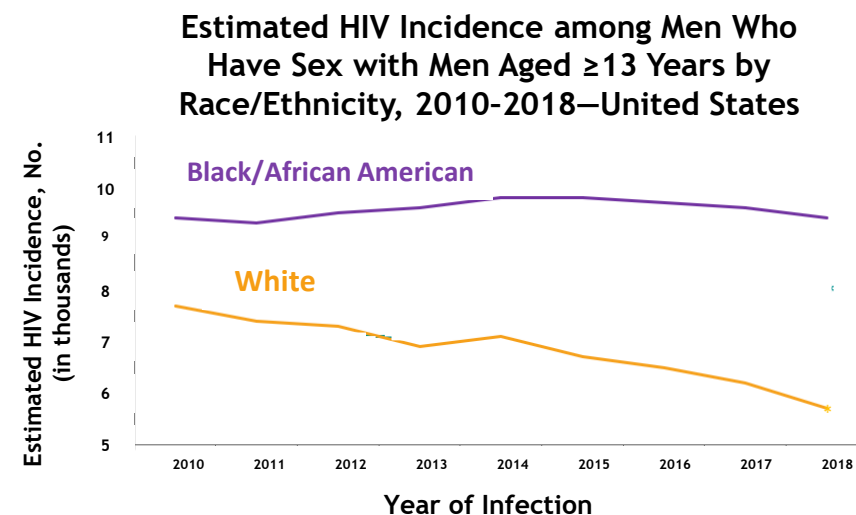


Figure 1: Number of new HIV diagnoses by US county, 2018



P. Sullivan et al. **Epidemiology of HIV in the USA: epidemic burden, inequities, contexts, and responses.** Lancet. Published online February 19, 2021

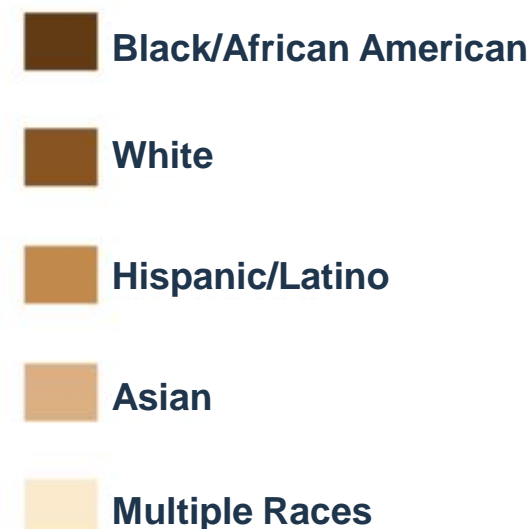
CDC Fact Sheet, **HIV in the United States by Region**, June 2020

CDC Fact Sheet, **HIV and African American Gay and Bisexual Men**, October 2020

CDC, **Estimated HIV Incidence and Prevalence in the United States 2014-2018**, May 2020.

# The HIV Epidemic in Black MSM and the Southern US: Diagnoses

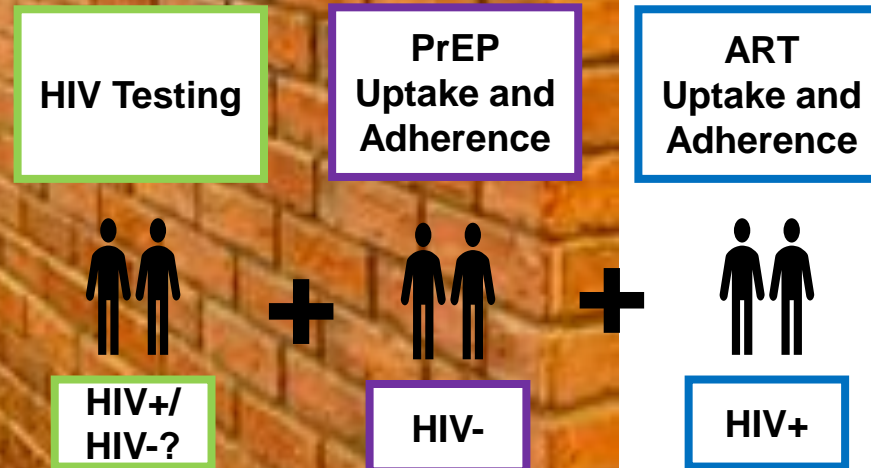
Blacks/African Americans in the South had the highest number of HIV diagnoses compared to other regions.



# Efficacious Biomedical Interventions



## Social Determinants of Health - Barriers to Testing, PrEP and ART



## Black MSM



HIV  
Transmission

# Implementation Framework

# Implementation Framework

**HIV PREVENTION EFFICACY**

# Implementation Framework

**HIV PREVENTION EFFICACY**

**CLINICAL INTERVENTIONS**

# Implementation Framework

## HIV PREVENTION EFFICACY

### CLINICAL INTERVENTIONS

- **HIV Testing**
- **HIV Pre-Exposure Prophylaxis**
- **HIV Treatment**  
*(includes all current FDA-approved products)*

# Implementation Framework

## HIV PREVENTION EFFICACY

## HIV PREVENTION IMPACT

### CLINICAL INTERVENTIONS

- HIV Testing
- HIV Pre-Exposure Prophylaxis
- HIV Treatment  
*(includes all current FDA-approved products)*

# Implementation Framework

## HIV PREVENTION EFFICACY

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## HIV PREVENTION IMPACT

### CLINICAL OUTCOMES

# Implementation Framework

## HIV PREVENTION EFFICACY

### CLINICAL INTERVENTIONS

- HIV Testing
  - HIV Pre-Exposure Prophylaxis
  - HIV Treatment
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## HIV PREVENTION IMPACT

### CLINICAL OUTCOMES

- Decrease HIV Transmission

# Implementation Framework

## HIV PREVENTION EFFICACY

### CLINICAL INTERVENTIONS

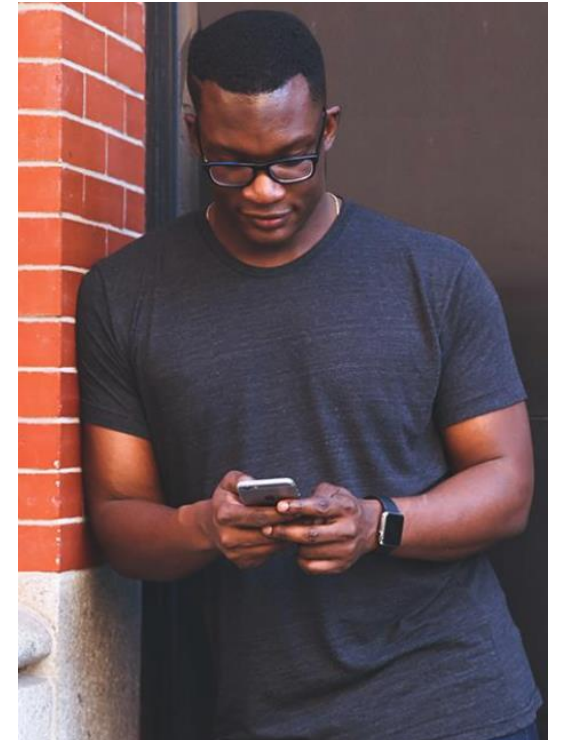
- HIV Testing
  - HIV Pre-Exposure Prophylaxis
  - HIV Treatment
- (includes all current FDA-approved products)*



## HIV PREVENTION IMPACT

### CLINICAL OUTCOMES

- Decrease HIV Transmission



# Implementation Framework

## HIV PREVENTION EFFICACY

### CLINICAL INTERVENTIONS

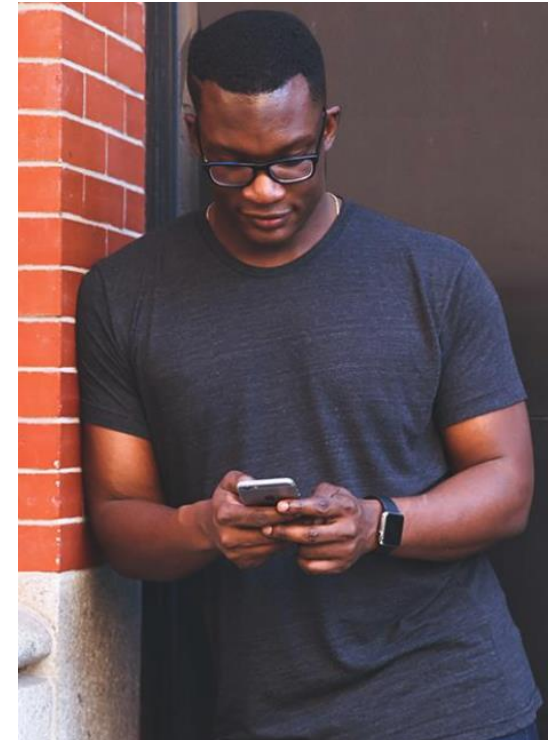
- HIV Testing
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## HIV PREVENTION IMPACT

### CLINICAL OUTCOMES

- Decrease HIV Transmission



# Implementation Framework

## HIV PREVENTION EFFICACY

### CLINICAL INTERVENTIONS

- HIV Testing
  - HIV Pre-Exposure Prophylaxis
  - HIV Treatment
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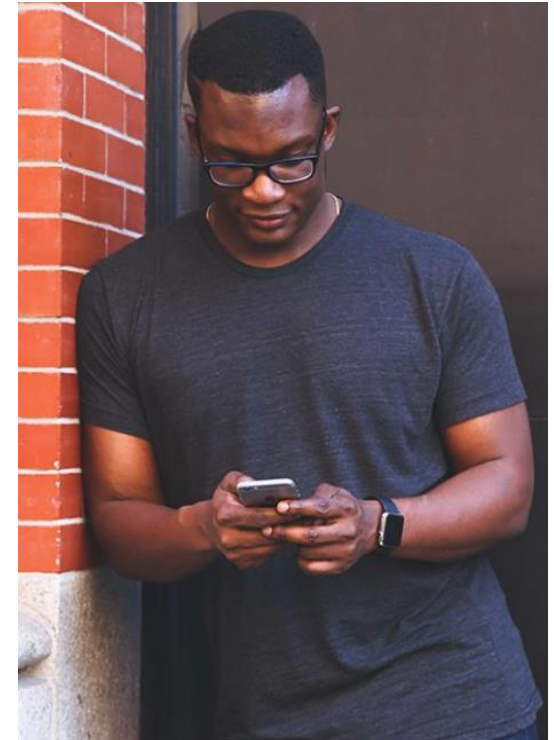


## IMPLEMENTATION SCIENCE

## HIV PREVENTION IMPACT

### CLINICAL OUTCOMES

- Increase HIV Detection
- Decrease HIV Transmission



# Implementation Framework

## HIV PREVENTION EFFICACY

### CLINICAL INTERVENTIONS

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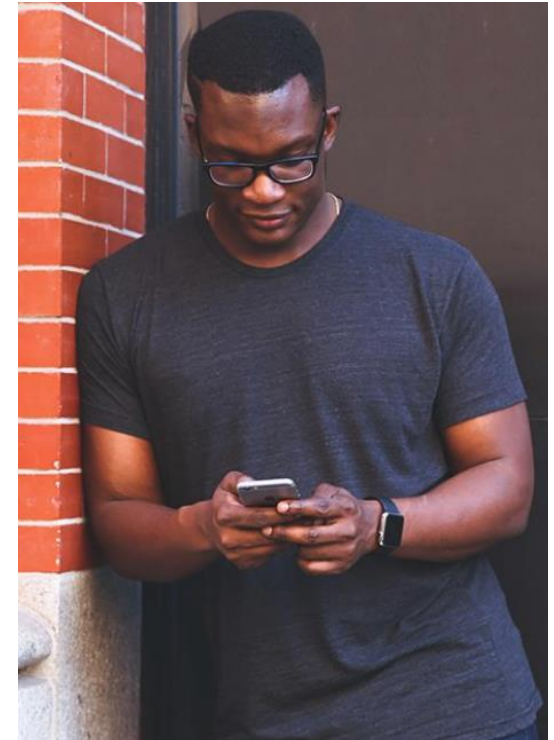


## IMPLEMENTATION SCIENCE

## HIV PREVENTION IMPACT

### CLINICAL OUTCOMES

- HIV Viral Suppression
- HIV PrEP Uptake



# Implementation Framework

## HIV PREVENTION EFFICACY

### CLINICAL INTERVENTIONS

- HIV Testing
  - HIV Pre-Exposure Prophylaxis
  - HIV Treatment
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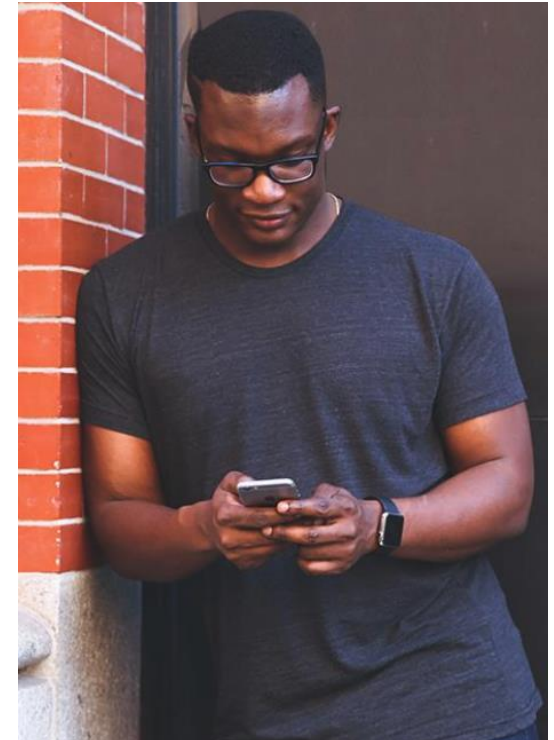
## IMPLEMENTATION SCIENCE

## HIV PREVENTION IMPACT

### CLINICAL OUTCOMES

- HIV Viral Suppression
- HIV PrEP Uptake

DETERMINANTS



# Implementation Framework

## HIV PREVENTION EFFICACY

### CLINICAL INTERVENTIONS

- HIV Testing
  - HIV Pre-Exposure Prophylaxis
  - HIV Treatment
- (includes all current FDA-approved products)*



## IMPLEMENTATION SCIENCE

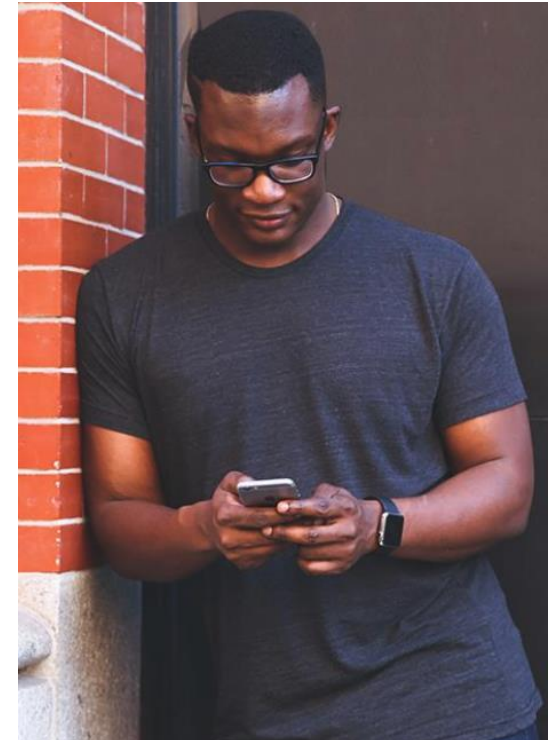


## DETERMINANTS

## HIV PREVENTION IMPACT

### CLINICAL OUTCOMES

- HIV Viral Suppression
- HIV PrEP Uptake



# Implementation Framework

## HIV PREVENTION EFFICACY

### CLINICAL INTERVENTIONS

- HIV Testing
- HIV Pre-Exposure Prophylaxis
- HIV Treatment  
*(includes all current FDA-approved products)*



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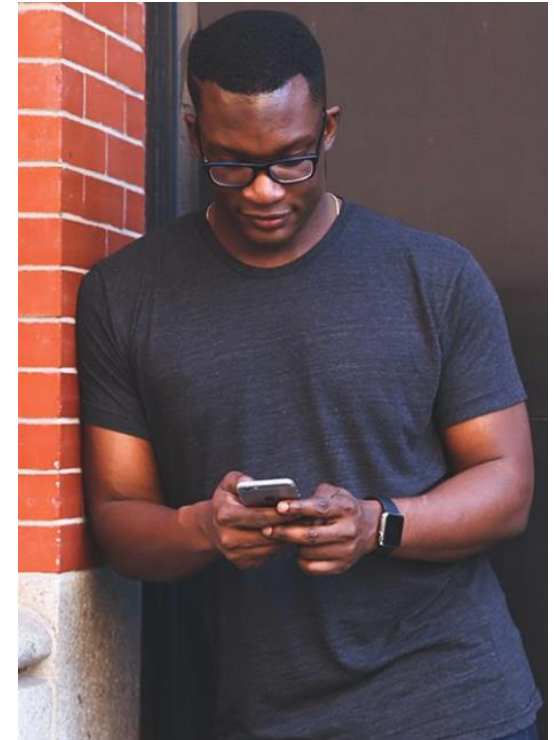
- Intersectional Stigma

## DETERMINANTS

## HIV PREVENTION IMPACT

### CLINICAL OUTCOMES

- HIV Viral Suppression
- HIV PrEP Uptake



# Implementation Framework

## HIV PREVENTION EFFICACY

### CLINICAL INTERVENTIONS

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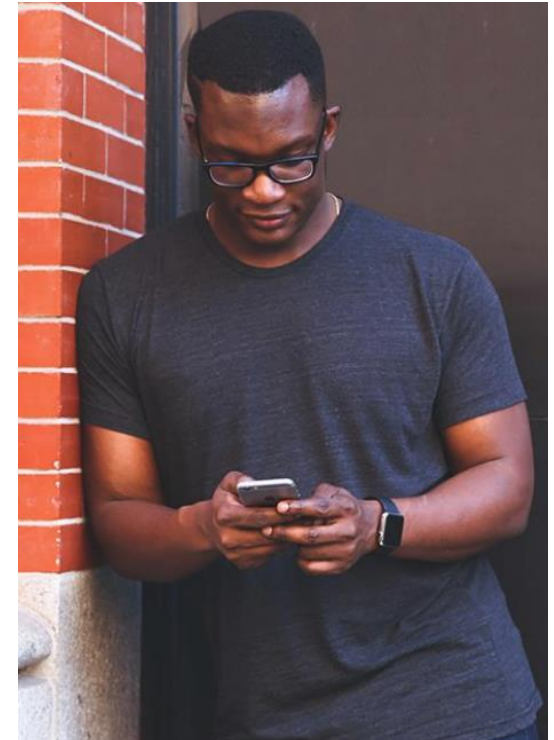
- Intersectional Stigma
  - Community-level

## DETERMINANTS

## HIV PREVENTION IMPACT

### CLINICAL OUTCOMES

- HIV Viral Suppression
- HIV PrEP Uptake



# Implementation Framework

## HIV PREVENTION EFFICACY

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- HIV Treatment  
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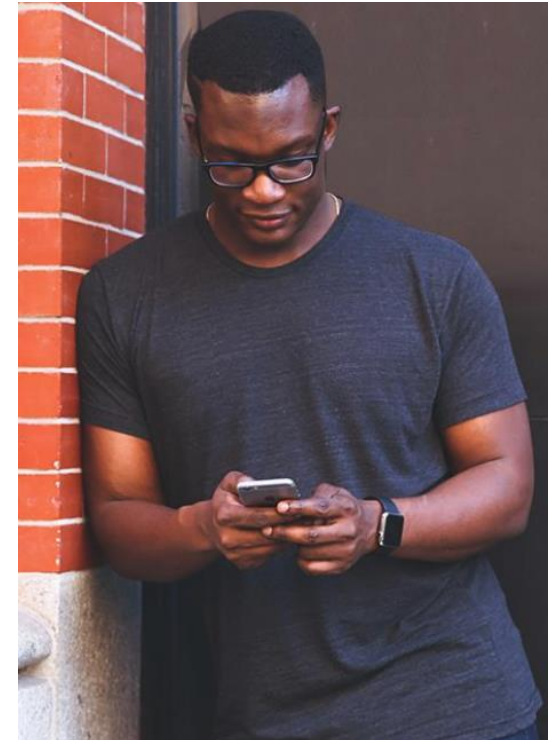
- Intersectional Stigma
  - Community-level
  - Healthcare facility-Level

## DETERMINANTS

## HIV PREVENTION IMPACT

### CLINICAL OUTCOMES

- HIV Viral Suppression
- HIV PrEP Uptake



# Implementation Framework

## HIV PREVENTION EFFICACY

### CLINICAL INTERVENTIONS

- HIV Testing
- HIV Pre-Exposure Prophylaxis
- HIV Treatment  
*(includes all current FDA-approved products)*

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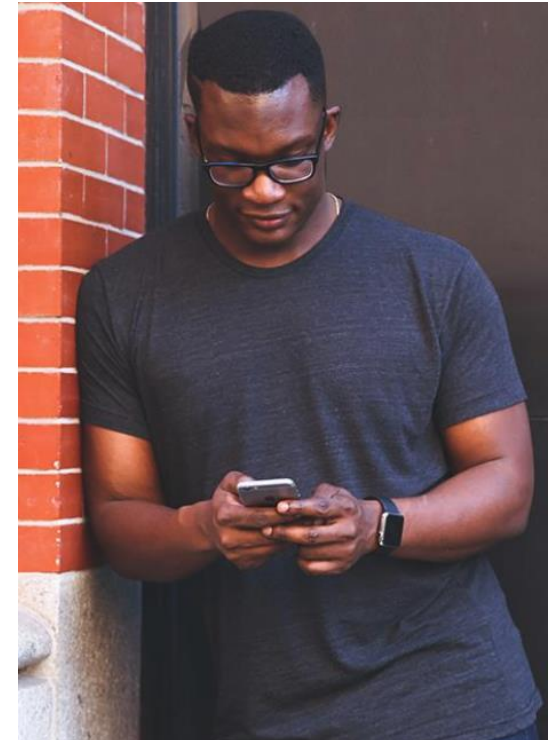
- Intersectional Stigma
  - Community-level
  - Healthcare facility-Level
- Culturally non-responsive services

## DETERMINANTS

## HIV PREVENTION IMPACT

### CLINICAL OUTCOMES

- HIV Viral Suppression
- HIV PrEP Uptake



# Implementation Framework

## HIV PREVENTION EFFICACY

### CLINICAL INTERVENTIONS

- HIV Testing
- HIV Pre-Exposure Prophylaxis
- HIV Treatment  
*(includes all current FDA-approved products)*

## IMPLEMENTATION SCIENCE

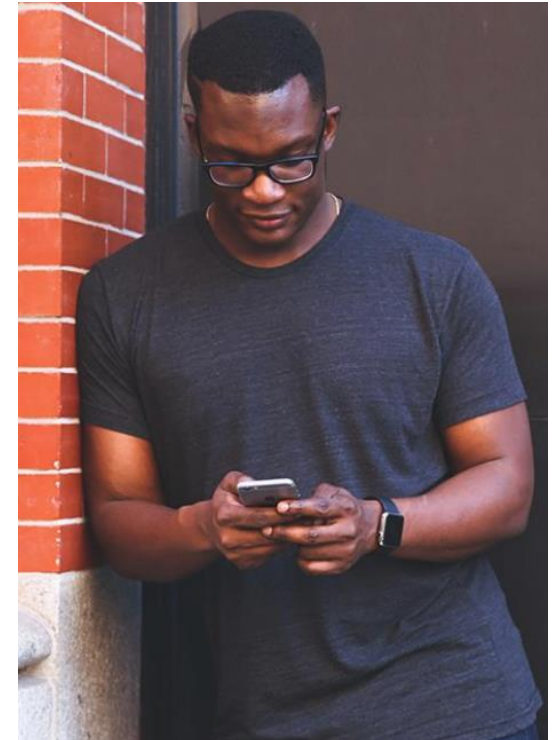
- Intersectional Stigma
  - Community-level
  - Healthcare facility-Level
- Culturally non-responsive services
- Structural barriers to social support

## DETERMINANTS

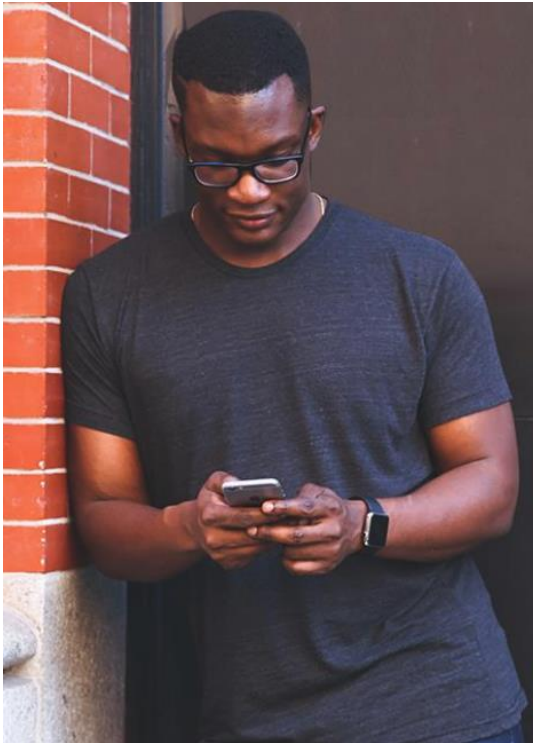
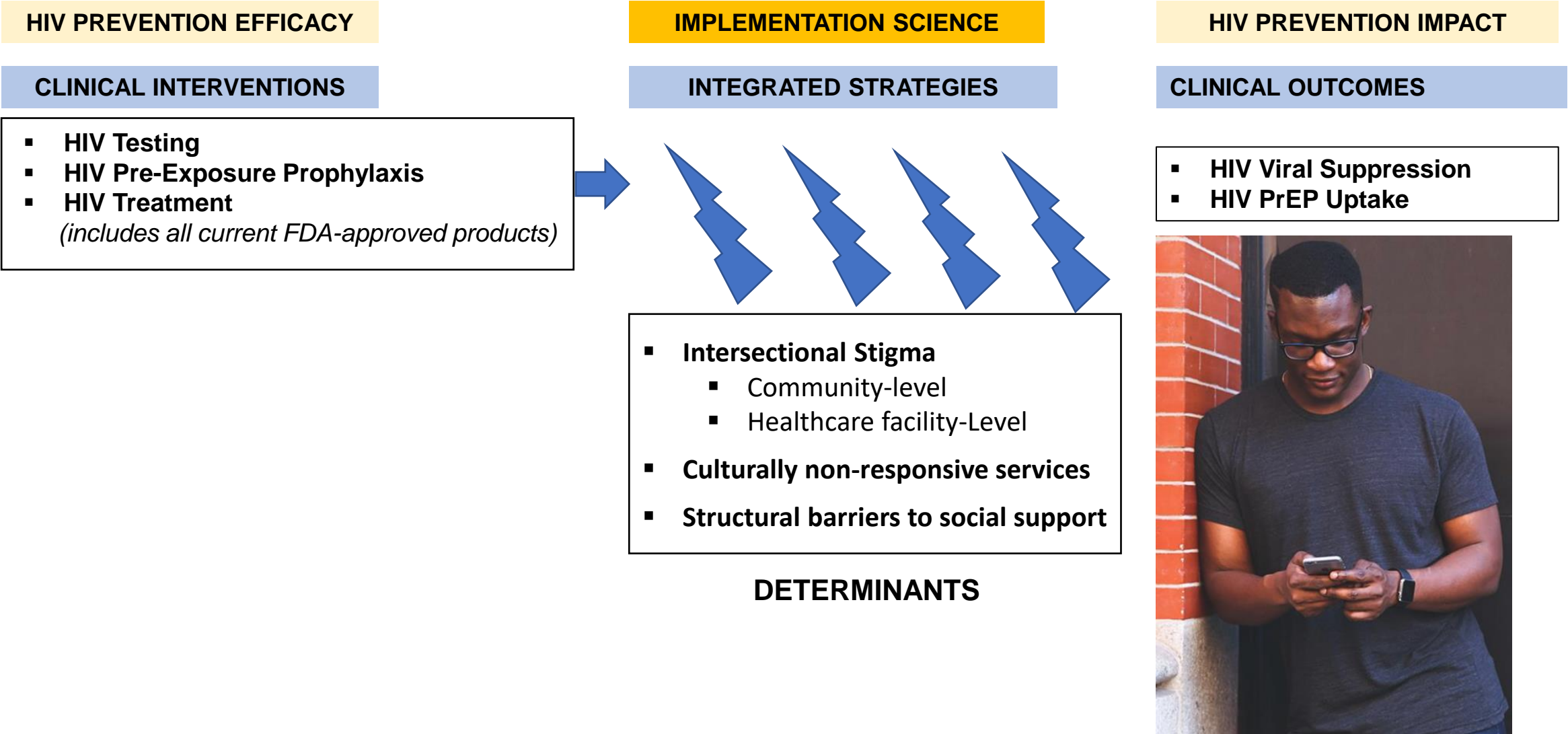
## HIV PREVENTION IMPACT

### CLINICAL OUTCOMES

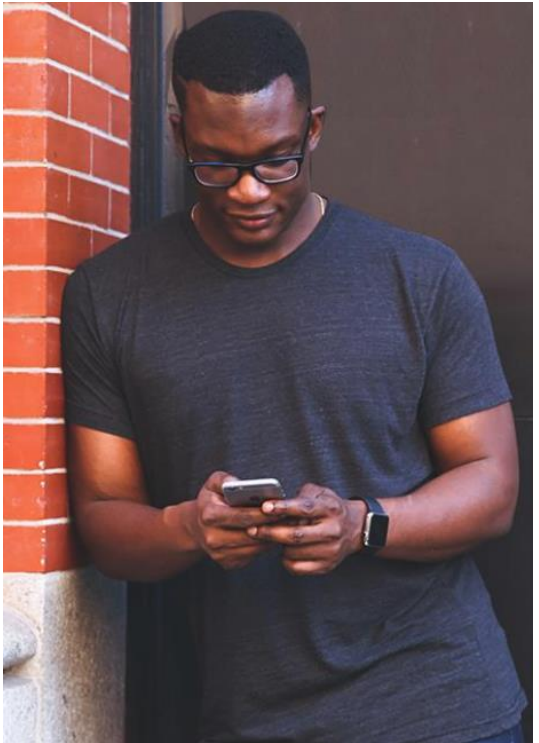
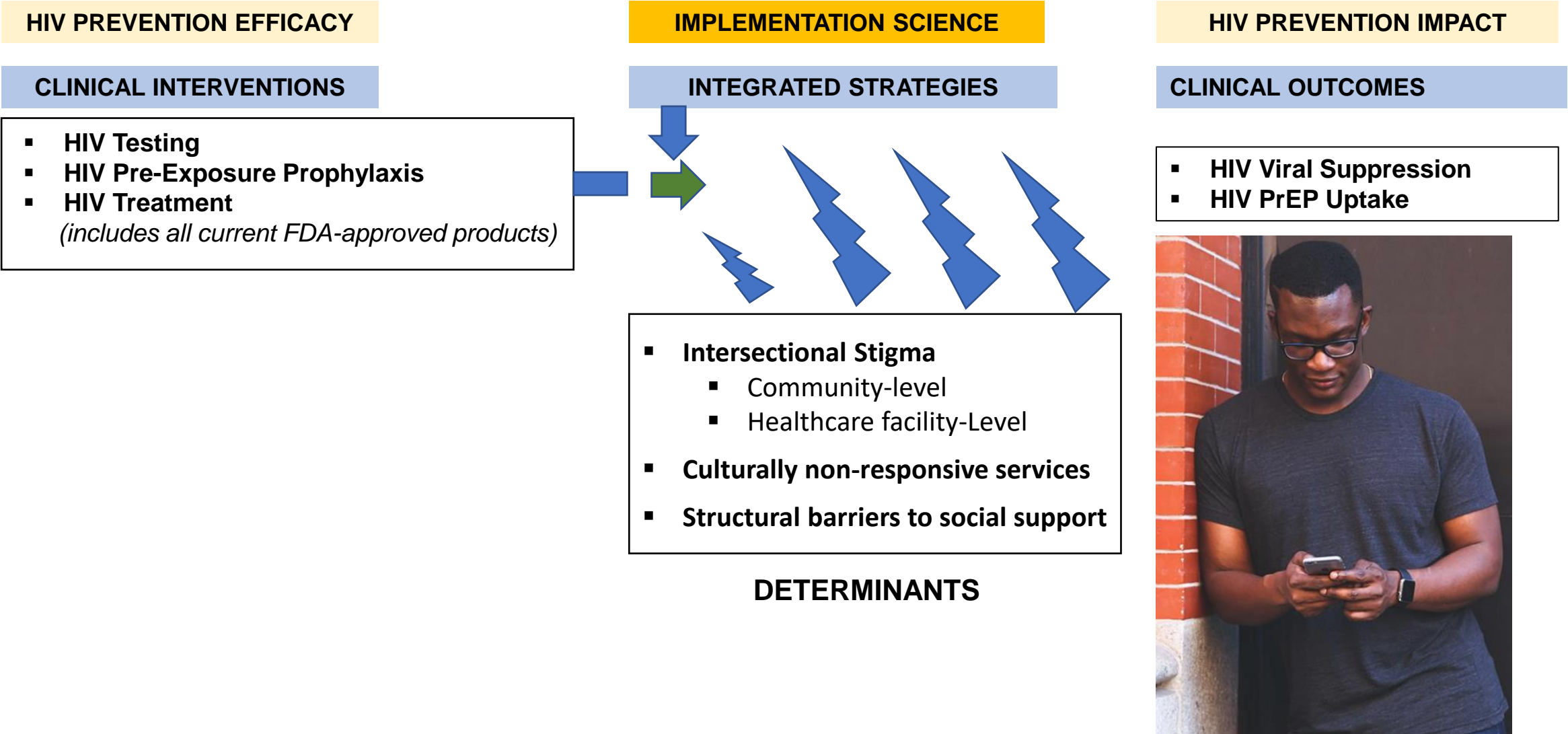
- HIV Viral Suppression
- HIV PrEP Uptake



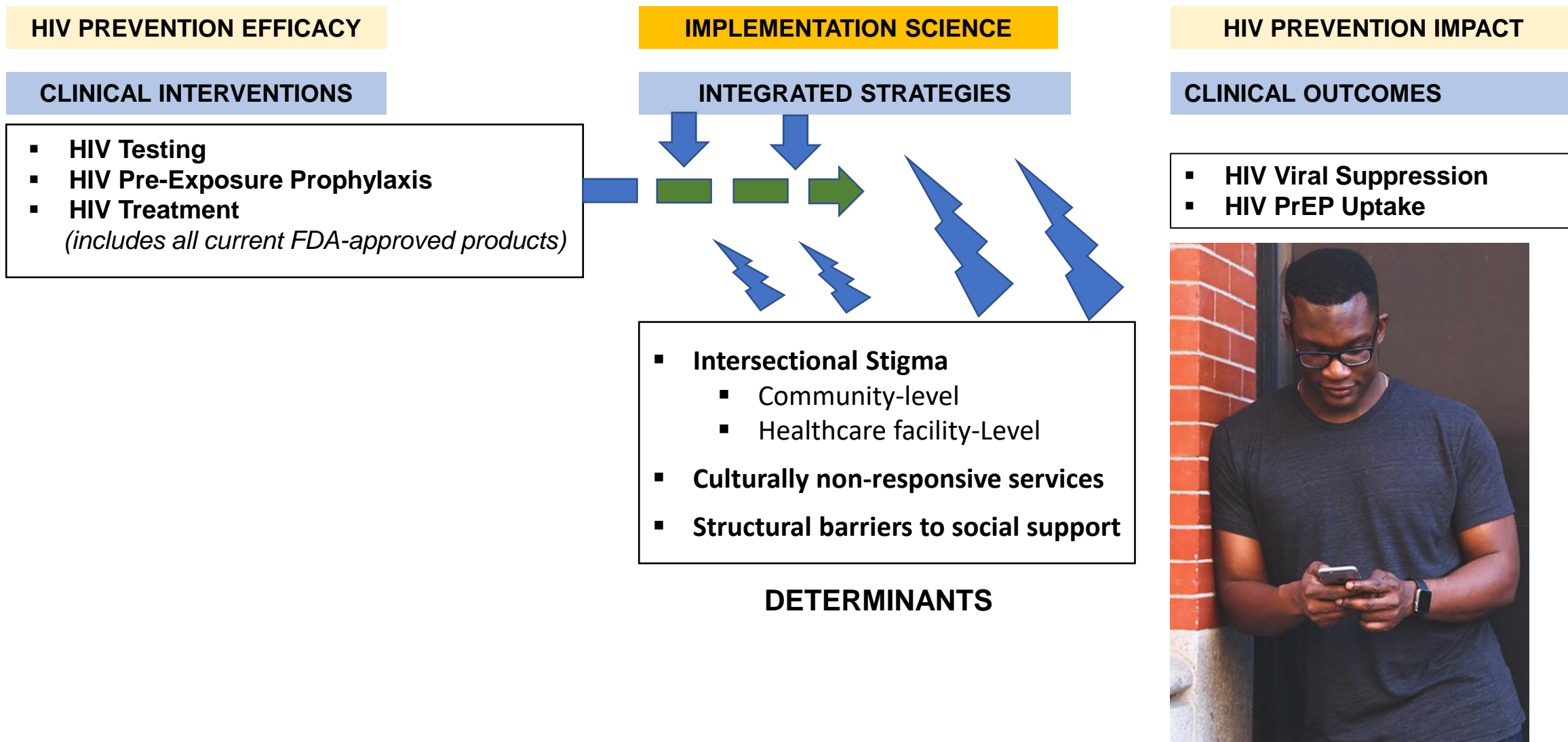
# Implementation Framework



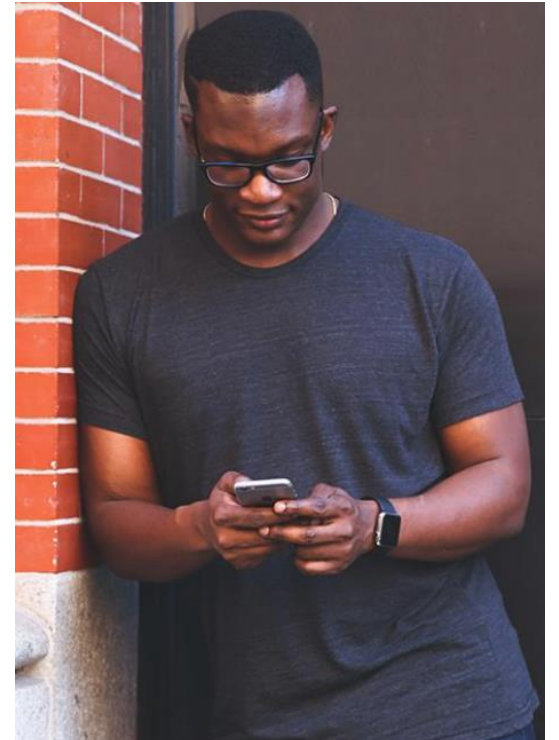
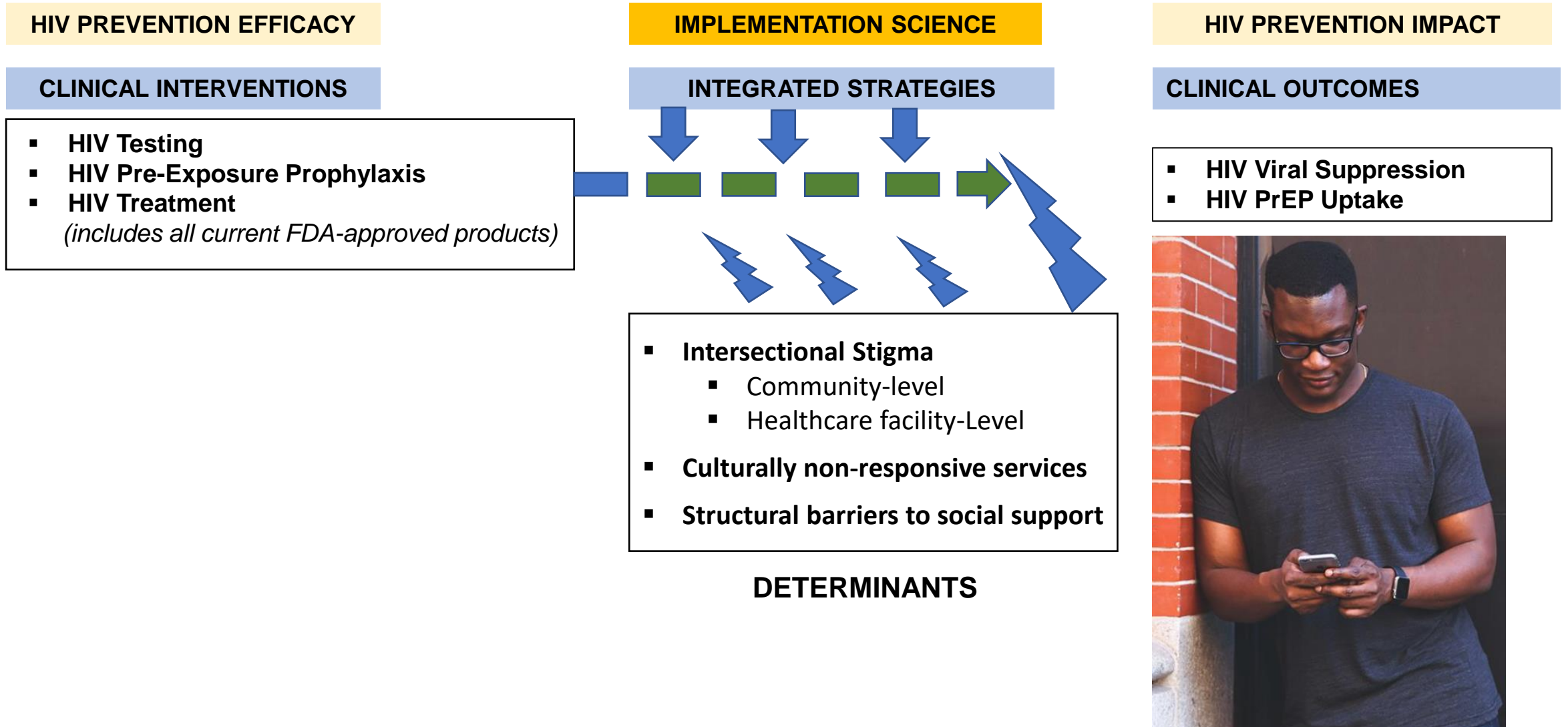
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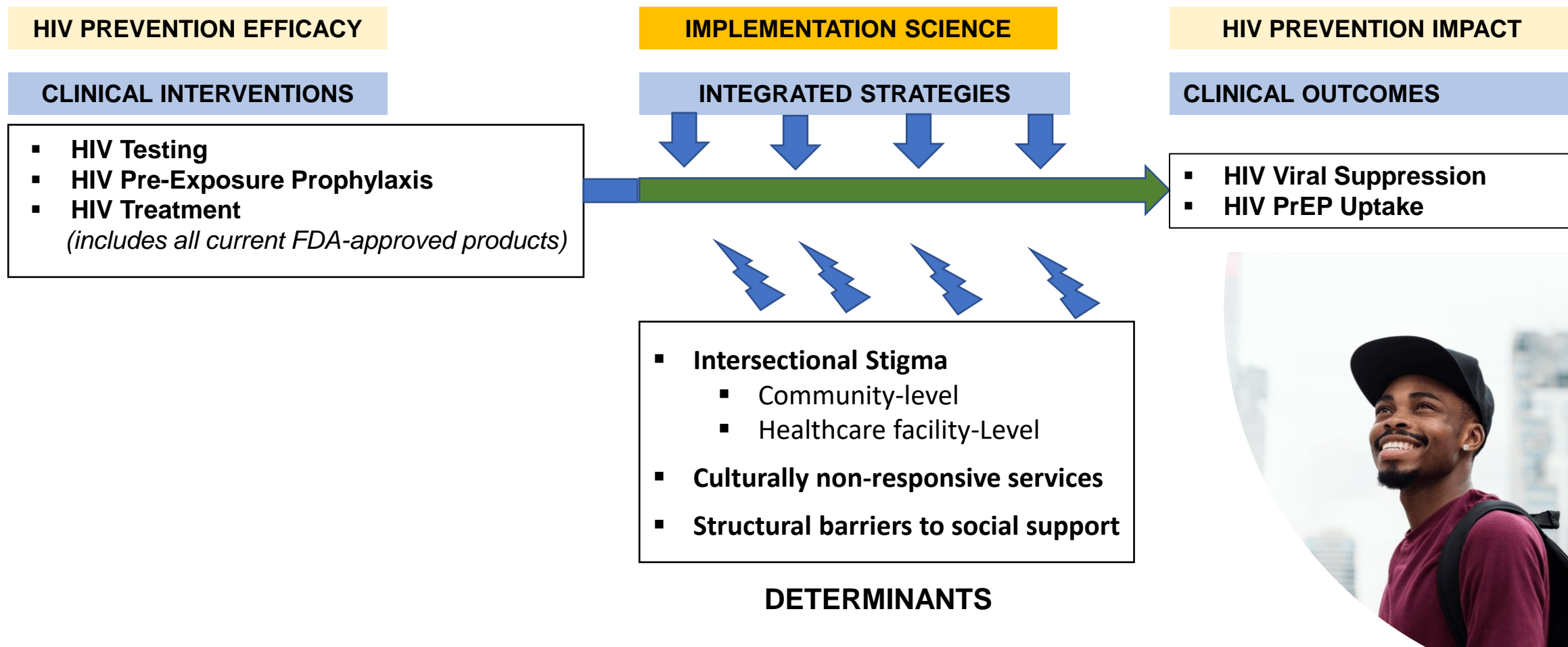
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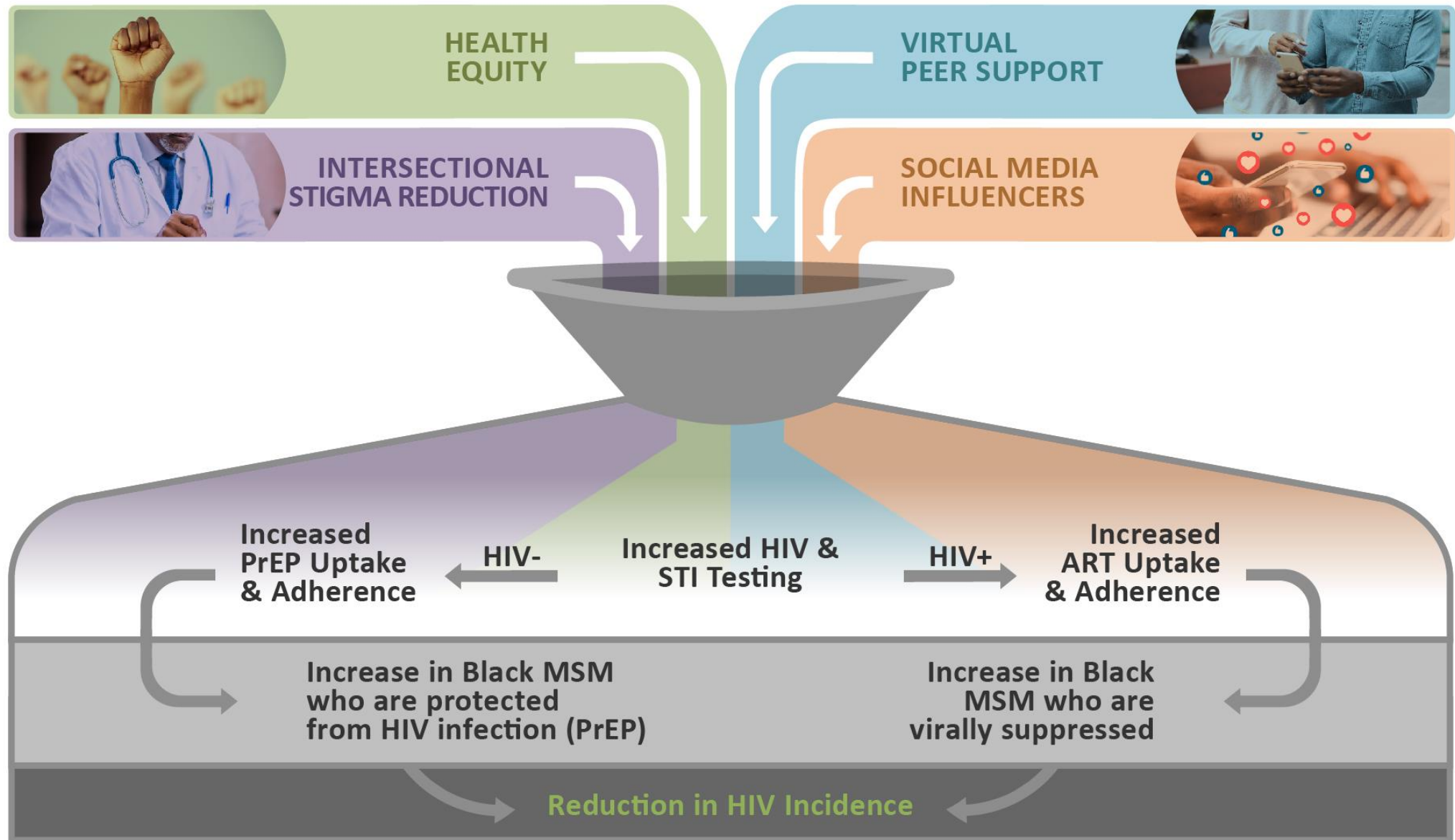
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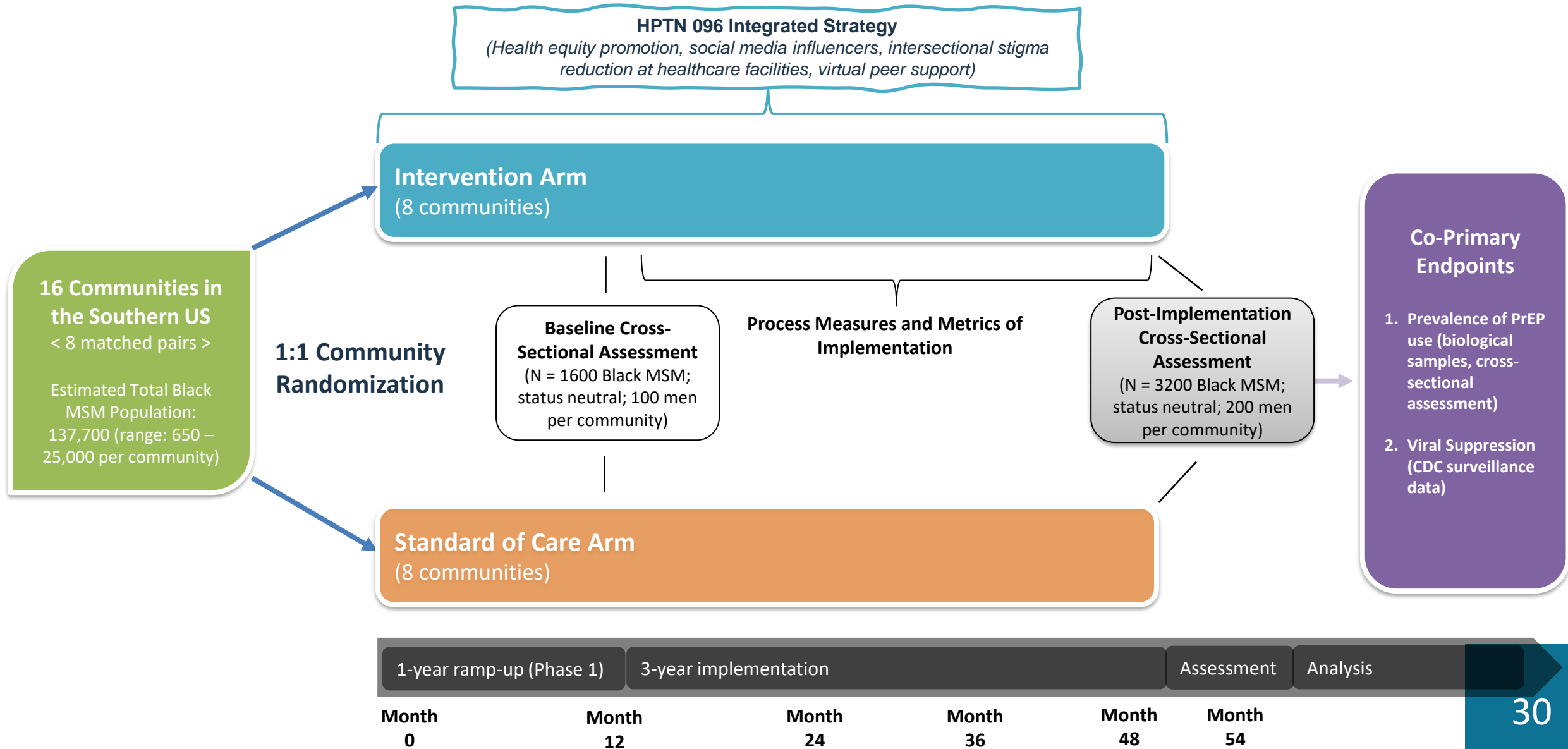
# Implementation Framework



# Integrated Strategy



# Study Design



# Co-Primary Endpoints

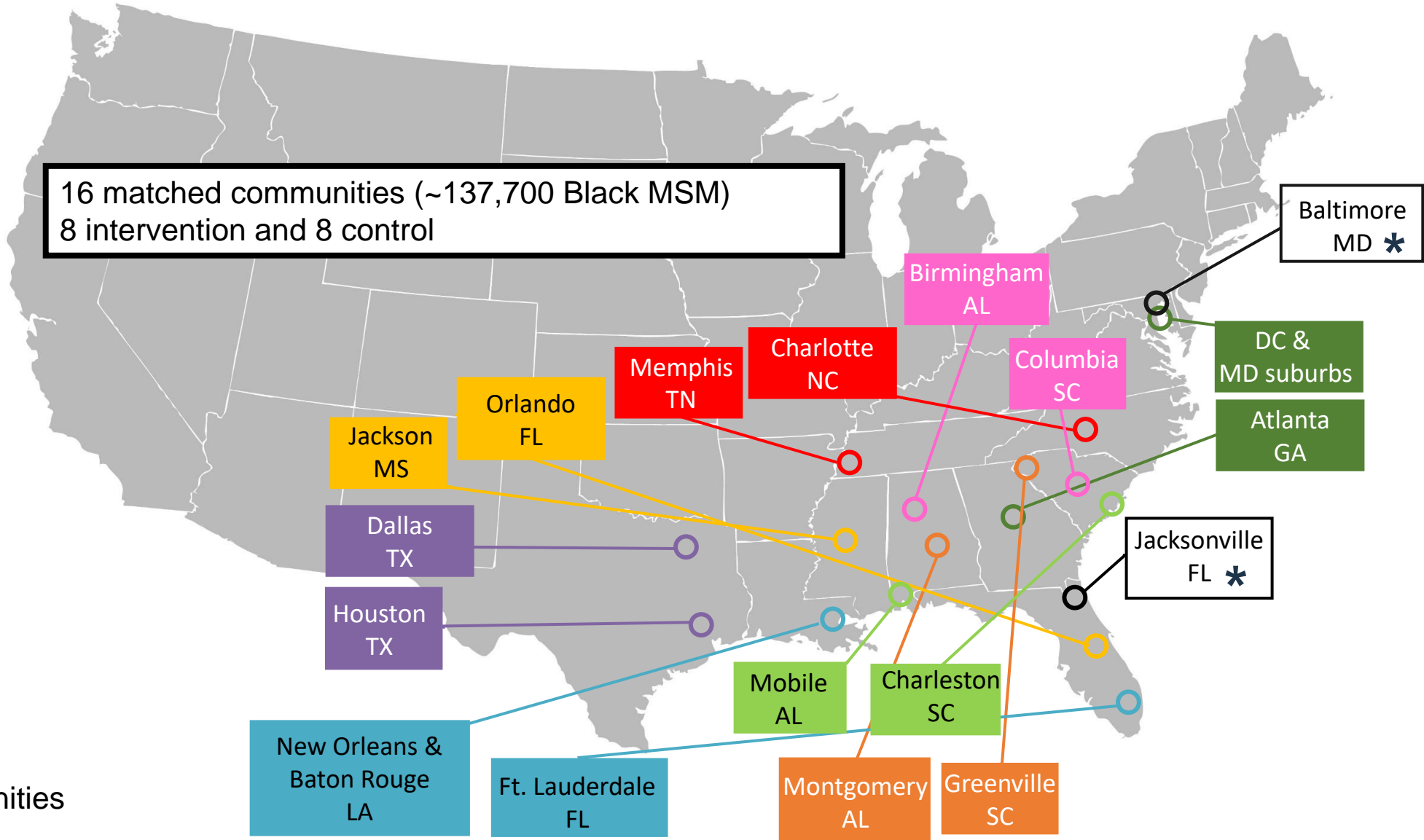


1. **Prevalence of PrEP use (biological samples, cross-sectional)**
2. **Viral Suppression (based on CDC surveillance data)**



# Study Communities

16 matched communities (~137,700 Black MSM)  
8 intervention and 8 control



\* Back-up Communities

# Community Engagement

- Community Listening Sessions
  - Georgia, South Carolina and Texas
- Community Strategy Group (CSG)
  - Guides community engagement activities
- Community Advisory Group (CAG)
  - 2 representatives from each study community
- Partnership with the Ending the Epidemic Committees in each study community



# Partnerships and Engagement

- NIH (sponsor)
- CDC
- HRSA
- Black AIDS Institute
- Ending the HIV Epidemic Councils in each potential jurisdiction
  - Public health departments, CBOs, clinics, universities
- Community Strategy/Advisory Group
  - National Black Gay Men's Advocacy Coalition
  - Black Gay Research Group
  - Association of Nurses in AIDS Care
  - National Black Nurses Association
- Gilead Sciences, Inc and ViiV Healthcare



# HPTN 096: PrEP and ART


- Working with partners to have the most effective and safe PrEP options available
- Already in discussion with pharma companies



# Study Timeline


**The study implementation will take place over the course of three years, after a one-year ramp-up period.**

2020				2021				2022				2023				2024				2025				2026	
Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2
PROTOCOL DEVELOPMENT				PRE-IMPLEMENTATION ACTIVITIES				1-YEAR RAMP UP				3-YEAR STUDY IMPLEMENTATION												ENDPOINT CROSS-SECTIONAL ASSESSMENT	
								BASELINE CROSS-SECTIONAL ASSESSMENT																	



**SWG review**

# Moving HPTN 096 Forward

- This is the right population.
  - The time is now.
- 
- HPTN 096 has a robust study design that can evaluate the impact of this integrated strategy on the uptake and use of biomedical interventions.

# Acknowledgements

**Study Co-Chairs:** Chris Beyrer, MD and Bob Remien, PhD

## Protocol Team:

**NIH:** Dale Burwen, David Burns, Michael Stirratt

**CDC:** Kevin Delaney, Irene Hall, Anna Satcher Johnson, Dawn Smith

**HRSA:** Keisha Bayne, Marcus Jackson, Angela Powell, Stacy Cohen, Shelita Merchant

**Black AIDS Institute:** Maximillian Boykin, Raniyah Copland, Elizabeth McGee, Rob Newells

**HPTN Ethics Rep:** Kathleen MacQueen

**HPTN LOC:** Theresa Gamble, Elizabeth Greene, Sherri Johnson, Ashley Mayo, Nicholas Hastings, Tanette Headen, Laura Long, Sam Alvarado, Kevin Bokoch, Gaby Salinas-Jimenez, Beth Farrell, Niru Sista

**Community Reps:** Marcus Bryan, Daniel Driffin, Melissa Turner

**HPTN SDMC:** James Hughes, Allison Meisner, Lynda Emel

**HPTN LC:** Susan Eshleman, Philip Sullivan

**Pharma Reps:** Christoph Carter, James Rooney

**EHE Committee Reps:** Melverta Bender, Krystle Cherry, Melvin Cauthen, Daniel Murdock

**Additional Team Members:** Bruce Agins, Marlon Bailey, Donte Boyd, Kendrick Clack, Donaldson Conserve, Patricia Coury-Doniger, Stephan Davis, Dustin Duncan, Errol Fields, Sheldon Fields, Charlotte Gaydos, Lisa Hightow-Weidman, Mandy Hill, Venton Hill-Jones, Christopher Hucks-Ortiz, Craig Hutchinson, Risha Irvin, Alex Keuroghlian, Tavell Kindall, Carmen Logie, Kenneth Mayer, Leisha McKinley-Beach, Leandro Mena, Ofole Mgbako, Kate Mitchell, Steve North, Gjvar Payne, Julie Pulerwitz, Justin Smith, Patrick Sullivan, DeAnne Turner, David Vlahov, Stephaun Wallace, Darren Whitfield

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